

U. S. PATENT APPLICATION

OF

WILLIAM REEVES

FOR

COMPUTER SYSTEM FOR
OPTICAL SCANNING, STORAGE, ORGANIZATION AND
ELECTRONIC MAILING OF MEDICAL RECORDS AND
OTHER SENSITIVE ORIGINAL LEGAL DOCUMENTS

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Name: William F. Reeves Signature: William F. Reeves

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**Invention Disclosure: COMPUTER SYSTEM FOR OPTICAL SCANNING,
STORAGE, ORGANIZATION AND ELECTRONIC MAILING OF MEDICAL RECORDS
AND OTHER SENSITIVE ORIGINAL LEGAL DOCUMENTS**

5 1. Abstract

 The invention disclosed herein relates to an improved method and system for the optically scanning, storage, management, retrieval and electronic mailing of a persons medical history on a 24 hour a day basis. The invention disclosed also encompasses unique and novel methods of verifying the authenticity of original
10 medical records via a physicians electronic signature, a means for standardizing and prioritizing the history and prior medical records of a patient so as to provide an edited or abbreviated medical chart for emergencies, a means of encrypting medical records for security, and a means of providing a unique alpha numerical identified code for each patient in the system and a means of 24 hour electronic and voice
15 retrieval of records using a unique telephone exchange system.

2. Background of the Invention

 Accurate recording keeping of medical records by medical "providers" (hospitals, physicians, clinics, labs, HMO's, PPO's, etc.) is a requirement of both
20 federal and state laws in the US, and is considered a "standard of care" in the medical industry. Providers must maintain records for a given number of years on a patient even after the patient has ceased using the services of the provider. Therefore, providers have a very large burden of maintaining accurate records, which include but are not limited to hand written physician charts, drug prescriptions,
25 x-rays, CAT scans, lab tests, blood and urine tests, eye glass prescriptions, etc. As one could imagine a hospital which handles patients with serious conditions would have a tremendous amount of records on hand in paper and x-ray film format which would have to be maintained for some years. Generalistics as well as specialists such and cardiologist, Neurologists, dermatologists, etc., are also under the same
30 laws to keep and maintain medical records for some reasonable period of time on each and every patient. Therefore, within the last several years many large

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hospitals and clinics have begun to use custom software packages for directly inputting patient charts into computer format to eliminate paper records. Other facilities have also chosen to put many medical records on microfilm or microfiche which is a more convenient and less bulky method of preserving paper medical records by photographing and reducing the documents onto film. Coupled with this record keeping burden are state and federal laws which restrict the amount a provider can charge for copies of medical records which are given at the request of patients. In most instances the charge for such copies of records is approximately \$0.40 - \$0.60 per page. Therefore, it is not hard to imagine that this record keeping burden is a very large administrative cost for a large provider and one which actually drains revenues from a provider, as opposed to creating revenues for a provider.

In contrast to the medical providers are the patients (consumers) who are entitled by law to have access to their medical records within a reasonable time period upon written request to the provider. As one could imagine the average individual and family has to keep track of many diverse pieces of medical records in order to try and maintain an individual set of medical records above and beyond what a provider keeps. This would entail the individual and family keeping track of drug prescriptions, eye glass prescriptions, x-rays, dental records, yearly physical examinations, etc., for an entire family. This would be a cumbersome and large set of records assuming the average citizen took the time to compile such records at all (most do not bother). As more and more individuals and families travel both domestically and internationally on vacations, for business and for relocations and second homes, having rapid access to medical records is all the more important in the event of medical emergency. If one was in a foreign country and had a medical emergency and did not have access to medical records this could either result in many unnecessary and expensive additional medical tests being performed for a new physician to access the individuals condition, and also could result in either the wrong treatment or substandard treat, which could result in adverse medical complications and/or death in the most extreme cases.

The purpose of the invention disclosed herein is to create a low cost, streamlined system which specifically meets the needs of the medical industry as well as

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the general public as the medical consumer to make the digitization, computer storage, retrieval, management, and electronic mailing of medical records efficient and low cost so as to fit into the present managed care environment in the US. The invention disclosed herein would also have benefits on a global scale for aiding in the transfer of medical records and data intra-country and intra-continent. The invention consists of a novel means of optically scanning ORIGINAL medical records into digitized binary format (original is emphasized because it is critical to the integrity of this system to have original patient medical charts and records which have a physicians original signature for authenticity), with unique software - organizing the digitized medical records into chronological order so as to prioritize and lessen the need for duplicate tests and records which would not necessarily be useful or applicable, with unique software assign a unique alpha numerical identifier to each patient and individual's medical records (separate from Social Security # and Birth date), with unique software positively identify the validity of "electronic signatures" of physicians and providers, through a stored electronic signature library, which are using computer software packages to generate medical charts and records (no hardcopy paper records), a means of rapid retrieval of medical records and the ability to electronically mail large amounts of medical records simultaneously to multiple individuals at multiple locations who require their medical records either for routine reasons or in the event of a medical emergency.

There has been a great deal of prior art in this area of medical records and using computers to organize and lessen clerical burdens. Many of the prior art patents focused mainly on ways to create software to do away with the traditional physician medical charts and to computerized medical charts whereby medical data would be inputted directly into a computer. One such patent is Doue 5,361,202 which teaches a computer system for managing the length of stay in a hospital of many patients simultaneously. The invention disclosed herein does not overlap or compete with the art that Doue teaches and the only thing they have in common is a computer system and medical data. The same holds true for Whalen 5,327,341 in which Whalen teaches a computer system and software for organizing patient charts. The main focus of Whalen is the format of the software which teaches the

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organization of computer medical charts with discrete fields and sections which aid in organizing the medical data. Whalen also claims the use of computer generated narrative reports which would be part of the physicians charts. Again, the inventions disclosed herein do not overlap or compete with the Whalen patent and the only
5 thing the inventions have in common is a computer and medical data. In Lavin 5,772, 585 a computer system is described again to facilitate and organize a physicians office which includes software for scheduling appointments, entering patient medical chart data onto a computerized chart, using a common graphic interface and creating data tables for the information. In Silvio 5,659, 741 a
10 computer system is taught to input large amounts of medical information onto computerized medical charts, transferring the data onto Hand Carried Storage devices, and for computerized searching of the files for character strings to compile health statistics and data. In Perry 5,241,466 a computer system is taught for storing living will documents presumably so they can be retrieved in the event of a
15 person's death. Neither Lavin, Silvio or Perry teach the art and system disclosed herein in this invention and this invention does not over lap or compete in any way with the inventions taught of Lavin, Silvio or Perry. Therefore, this invention is unique and novel and different from all prior art described.

20 3. Summary of the Invention

Please reference figure 2. The invention comprises hardware and software for the optical scanning of original paper and/or film (x-ray, CATscan) medical records and charts. An alternative serial or parallel computer port allows for digitized data to be inputted into the system computer from a pre-existing digital
25 medical data base. Smart software, which is an integral part of the system, verifies that each patient chart being transferred from the pre-existing medical database has an authentic and original electronic physician signature to verify the authenticity and originality of the medical chart. This is a critical part of the invention disclosed because more and more hospitals, clinics and group practices are using medical
30 chart software to enter patient records which eliminates the need to keep a hard copy record. Because hard copy records, with the physicians original signature are

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not being kept for records, this opens up the legal question of what defines an "original" medical record and physician signature, which have not been tampered or altered. One solution which has been mandated by federal and state laws has been the creation of electronic signatures for each physician which would be a unique alpha numeric identification code. These electronic signatures would have to accompany medical charts, drug prescriptions, medical tests, etc., to verify the authenticity of the medical data and to ensure the data was not altered or tampered with. Therefore, the inclusion of a means of storing an alpha numerical library of physician electronic signatures and comparing those signature to the signatures on electronic charts is an integral part of the integrity of this invention. Also an integral part of this invention is the optical scanning of only original hardcopy medical records with original signatures of physicians. Again this is critical to the integrity of the system from a legal liability point of view. Once the hard copy record is scanned into the system the smart software can assign the electronic signature of the corresponding physician from the internal identifier library to this new digital patient document and the electronic signature will follow the digital document for its entire life for authenticity.

Once the medical records of a patient are entered into the main computer system they are organized in a priority based on chronological order. This means that if an individual had three chest x-rays over the last 10 years the most recent x-ray is given a priority in the patient's file over the other two x-rays as it is the most up-to-date document. This is not to say that the other x-rays have no value, which they do because they can be an important historical document to show the gradual progression of such diseases as chronic bronchitis, emphysema, lung cancer from smoking, etc. Other factors may also effect priority such as serious pre-existing medical conditions and tests and or medical charts which document such conditions. Also, severe drug reactions and allergic reactions and other emergency medical data would take a priority in the organization. The invention also comprises a plurality of data management interface stations (work stations) where many operators can be inputting, accessing and retrieving medical data simultaneously without interfering with each other. The work stations would be comprised of computer

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screen monitors, keyboards, and any other combination of audio visual computer controls such as voice recognition microphones and headsets to facilitate computer commands and controls. Other software and hardware is used to allow for a plurality of work stations to transfer medical records and data onto computer disks, Compact
5 Disks, ZIP disks, or any other appropriate media for patients, including hard copy prints or films, and or physicians to access and store patient medical records. The plurality of work stations for the creation of records on computer disks, printers, films, etc., allows for many operators to access and retrieve medical records simultaneously without interfering with each other. One of the most important
10 aspects of the invention disclosed is the telephone interface exchange. This hardware which is interfaced with the computer system allows for a large plurality of telephone lines to be interfaced to the system. Because medical emergencies occur 24 hours a day, 365 days a year this invention is designed so that there is 24 hours a day, 365 day a year access to medical records in a variety of ways. If a patient,
15 physician, clinic or hospital, etc., wants to retrieve a specific medical record they have the option of calling a toll free number or e-mailing the request over the telephone lines through the telephone interface exchange. 24 hour a day attendants can field the request, retrieve the records and either e-mail the records, modem the records, send them over high speed optical cable lines, or any other appropriate
20 tele-communications media. Another option designed into the telephone interface exchange and system software allows for patients, physicians, and other authorized personnel and care givers to call into the system 24 hours a day and, using a unique PIN number or alpha numerical identifier, access medical records and data and retrieve them via the Internet (the system could be up on a Web page for care givers
25 and other authorized people to access but only with tight security and PIN numbers), e-mail or via a modem line. The 24 hours a day access to this system and the telephone links to e-mail and modems affords both care givers and patients rapid access to medical records in the event of an emergency any where in the world at any time of day or night which is a critical aspect of this invention and its utility to the
30 medical industry as well as consumer. The direct link feature of this system allows for frequent user to be directly tied into the system using dedicated telephone lines,

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modems, coaxial cables, etc., with the proper security codes and protections. Also, the invention allows for new or updated medical records and data to be sent into the system through the telephone exchange interface in a 24 hours a day manner via the smart software which can recognize the entry of new data, verify the authenticity of an electronic signature of a physician and allow the data to be entered into the computer system.

Figure 1

Figure 1 shows a flow diagram of the software used in the system which is an integral part of this invention used to organize, authenticate, retrieve and electronically mail medical records. As previously described medical records data can either be entered from a pre-existing electronics database or optically scanned into the system from hard copy patient records. If pre-existing electronic records are entered into the system, smart software within the system will access a physician electronic signature Library and cross check the authenticity of the electronic signature of the attending physician on the records. If the electronic signatures do not match the records are prevented from entering the system until further checking can occur by an attendant. If the electronic signatures do match then the records are approved for processing and a unique patient alpha numerical identifier is added to the records for rapid retrieval within the system. This unique identifier could be the patients social security number plus an added numerical digits to create a unique new identifier. Other alpha numerical identifiers could also be used. Hard copy records and films which are optically scanned into the system are processed in a similar fashion. Once the software assigns the unique identifier to the records they are allowed to enter the computers central processing data base. In this area the software prioritizes the records as previously described by chronological order to eliminate the need for duplicate records of the same tests. Also, records are prioritized based on the severity of any pre-existing medical conditions, severe allergic reactions and severe drug reactions so these records are given a priority in the event they are retrieved in an emergency when time is of the essence. The software has the ability to assign either a weighted average priority to records based

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on the severity of a condition or a numerical priority scale from 1-10 based on severity. This will speed up the recall of critical medical records in an emergency. Records which are old and dated and not readily applicable can be given an "A" coding, or any other appropriate codes, which signifies "Archive" purposes only and thus will not be considered necessary in an emergency. Again, records can either be retrieved from the system manually by an attendant or automatically by an authorized personal using the 24 hour telephone access and PIN number routine. When an attendant wants to retrieve a specific record all they need do is enter the patients name or unique identified code and the software will automatically retrieve the records via a data request command message. Again, records will be retrieved in order of priority so the most critical information for a health emergency will appear first. Scroll and menu features with the software will also allow an attendant to view a patients records by "page" and retrieve only the data which may be appropriate for a given request, e.g.: the patient only requests their most recent dental x-rays.

When a 24 hour a day caller uses the telephone exchange service they can access patient 15 records by choosing from several different venues- Web Page, automated voice service, dedicated confidential direct link service or by speaking directly to an attendant. The confidential Web Page allows authorized user to access patient records only by having the authorized codes to several redundant security steps, including but not limited to an electronic physician signature and a system PIN number, to ensure security and privacy. The Web Page will be menu driven and allow an authorized user to select specific patients and specific medical records of a patient for speed and ease of use. Patient records can be downloaded directly from the system to the authorized users computer using the modem and telephone links to save time and eliminate the need for paper records and mailing. The 24 hour a day Voice System is organized so that an authorized caller has to pass through several redundant security steps including but not limited to a physicians electronic signature and a PIN number to access the system. The Voice system is set up so that the user can either speak the words into the system and the software will recognize the words and numbers, or the caller can punch them in using a touch tone phone. Once the user has been cleared for security they can request a specific

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patient record which will be stored in the software in the form of an order or request. In the case of an emergency, where records must be retrieved immediately, the system software will be capable of faxing or modeming records directly back to a caller if they are using the modem or fax line when calling. Otherwise orders for records will be processed in chronological order by attendants on a routine basis. The Dedicated Direct Link allows frequent users of the system to have direct access through either dedicated modem, LAN, Watts or other telephone lines Direct Link users would have custom software loaded into their computers which would be compatible with the host computer system and allow for direct access to patient records, but the same redundant security measures, including but limited to electronic signatures and PIN numbers, would have to be used to have access to patient records. As an alternative to the above a user could call 24 hours a day and talk directly to an attendant who could retrieve files and e-mail, modem, fax, etc.. them anywhere in the world. The same user security precautions would apply.

Detailed Description of the Invention

Reference Figures 1 and 2.

The invention disclosed is comprised of both hardware and software which are both integral to the invention. The hardware includes a unique and novel high speed, high resolution optical scanner 1 which is capable of scanning both text documents as well as film documents such as x-rays, CATscans, etc., with proper resolution to maintain the documents diagnostic quality and accuracy. The unique optical scanner disclosed in this invention is capable of scanning the unique patient identifier code into the body of the patient record, as well as the electronic physician signature, as the scanner simultaneously scans the document into digital data. This unique feature is accomplished by the smart software embodied within this invention. The scanner will be capable of scanning both Black and White and full color documents and films. The hardware also includes an Interface Controller 2 which is comprised of an enclosure, multiple digital and analog inputs, and multiple digital and analog outputs. The purpose of this Interface controller is to allow for a plurality of sources to input data into computer system 4 without the input signal interfering

with each other, canceling each other or corrupting the signal and integrity of each other. This plurality could include any number of Optical Scanners 1 and/or any number of Existing Electronic Medical Data Bases 3. The connections to and from the Interface Controller 2 can be serial, parallel, optical, co-axial or any other appropriate type for the transfer of large amounts of analog and digital data. The Existing Electronic Medical Database 3 can be any where in the world physically and can be connected to the Interface controller via telephone link, co-axial cable link, wireless AM or FM transmission or any other type or form of communications link for the transmission of data. The computer system could be any appropriate type of computer including but not limited to a laptop, Personal Computer, Work station or main frame computer. The computer system would consist of a sufficient amount of RAM random access memory to process multiple data inputs and requests, Hard drive or magnetic drive central memory for storing large amounts of digital medical records, and sufficient video hardware and software to simultaneously support one or multiple users and attendants to the system. The computer also has a magnetic tape drive back up which allows for redundant magnetic tape back ups to be made of the stored digital data, to be kept in a separate and safe location, as a precaution against hard drive failure or data corruption's and viruses. A Data Management Interface 5 is similar to the Interface Controller 2 in that it allows multiple attendant to work simultaneously to input and retrieve medical data without the signals interfering, corrupting or cutting off other signals. In essence DMI 5 is a type of digital switching Bus or digital switchboard to route and Queue the signals between the attendant stations 8 and the Main Computer System 4. The attendant stations 8 are comprised of suitable computer screens, keyboards, mouse controls and microphone and earset controls to send command signals to the computer system either using keyboard commands or voice commands which are converted to digital command signals by the system software. A separate Interface controller 6 is used, in the same way as Interface Controller 2, to route multiple input and output commands and signals to and from the main computer and the Telephone Interface Exchange 7. The Telephone Interface 7 consists of a plurality of telephone and communications lines which are capable of two way transmission and will send and

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receive data signals to and from the system as well as route 24 hour a day emergency calls and routine records requests. The Telephone Interface exchange 7 and Interface Controller 6 work in tandem to route and prioritize incoming and outgoing telephone signals so as to prevent signal corruption, cross talk and interference and ensure smooth operation. The system includes a variety of output devices for either making hard copy prints of original digitized records or for putting records onto computer disks or magnetic tape back ups. The quality and resolution of the printers and output devices is critical to maintain the integrity and quality of the of the original tests, x-rays, etc., as they are passed from one medium to another. Medical Diagnostic quality and integrity must be maintained on all variations of digital and hard copy records. Output device can include but are not limited to Medical Disk or Card Creation 9, High Resolution Printer 10, High Resolution Thermal Printer 11, Magnetic Tape Drive 12 or any other suitable output device for storage and/or diagnostic quality copies.

Figure 1 Shows a detailed flow diagram for the overall control software of the system. Digital Medical Record Data is entered into the system either from Optical Scanner 1 or Existing Database 2. In the case of Optically Scanned data 1 the smart system software analyzes the data and assigns a unique alpha numerical system identifier code from the User Code library 7 to each patient record. Also the system checks for an electronic physician signature, and if none exists, selects the correct electronic signature from the internal library 3. In the case of pre-existing Electronic Data 2 the software checks the validity of the electronic signature assigned to each patient record from the internal electronic signature library 3. If the electronic signatures match, the patient records are accepted into the system and assigned a unique patient ID from the internal library 7. If the electronic signature do not match the data is rejected from the system and an attendant is flagged. Once data is accepted to the system from either the Scanner 1 or the Existing Database 2 it is stored in the central storage media 5. As previously described the system software analyzes the patient records and using a chronological order priority routine 10 prioritizes the patient record for ease of retrieval in an emergency. At any time patient records can be retrieved 11 using the unique identifier code for rapid

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identification and retrieval using request messages 9 sent from either attendants, 24 hour callers or direct link access. The 24 hour automated Message Interface 15 allows any number of telephone and other communications signals to enter the system through either e-mail 17, Internet 18 or modem 19 or any other appropriate communications means. Calls are routed through the Interface 15 to their appropriate destination of either the system Web Page 12, the 24 hour voice system 13, or the Dedicated Direct link 14. Web Page 12, Voice system 13 and Direct Link 14 are all capable of sending data retrieval commands to the central storage system 5 but only with the proper security codes as previously described. The 24 hour attendant service 16 is also capable of inputting and retrieving data and records from the system on a routine basis.

Figure 3 shows a typical organization and priority routine for a given patient record. As previously described records are organized into digital pages with each page being numbered. The unique identifier code and physician electronic signature are embedded in each page of the records for authenticity and security (similar to the watermark on US currency). Records are prioritized by giving emergency and serious pre-existing condition tests and records priority. Also, duplicate tests are prioritized in chronological order. This saves retrieval time in an emergency and/or a routine situation.

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